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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/491,500	01/26/2000	Keith L Black	CEDAR043-453	8610

7590 09/09/2004

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EXAMINER

FALK, ANNE MARIE

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 09/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/491,500

Applicant(s)

BLACK ET AL.

Examiner

Anne-Marie Falk, Ph.D.

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 11-18, 97-100 and 106-199 is/are pending in the application.
- 4a) Of the above claim(s) 97-100, 106-109, 124-138, 140-152 and 156-199 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 11-18, 110-123, 139 and 153-155 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/7/03</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1632

DETAILED ACTION

The response filed June 24, 2004 has been entered. Applicants' election without traverse of Group I, Claims 1-6, 11-18, and 110-166. Applicants further elect carboplatin as the medicant species for examination. The elected invention is drawn to a method of delivering a medicant to an abnormal brain region in a mammal.

Claims 1-6, 11-18, 97-100, and 106-199 are pending in the instant application.

Claims 97-100, 106-109, 124-138, 140-152, 156-166, and 167-199 are withdrawn from consideration pursuant to 37 CFR 1.142(b), as being directed to a nonelected invention or nonelected species, there being no allowable generic claim.

Accordingly, Claims 1-6, 11-18, 110-123, 139, and 153-155 are examined herein.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 3, 2003 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 11-18, 110-123, 139, and 153-155 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one

Art Unit: 1632

skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a method of delivering a medicant to an abnormal brain region in a mammal comprising administering an agonist of an ATP-sensitive potassium channel, under conditions and in an amount sufficient to increase the permeability to the medicant of a capillary or arteriole delivering blood to cells of the abnormal brain region, and administering substantially simultaneously with the agonist the medicant, so that the medicant is delivered selectively to the cells of the abnormal brain region compared to normal brain regions. The claims are further drawn to limitations of the broad scope of the method, including type of abnormal brain region (stroke-affected, ischemia-affected, tumor, etc.), type of delivery (intracarotid injection, intraarterial injection, etc.), type of medicants, dosages, type of mammal, and rates of delivery.

The enablement rejection is directed towards the intended use of the method of delivery. The specification is directed entirely towards using the claimed method for treatment of a disease or disease state. Thus, the only asserted utility, particularly for the delivery of the various medicants mentioned in the claims, is for producing a treatment effect.

The specification fails to provide an enabling disclosure for the treatment of any disease or disorder. The art of drug delivery and production of a treatment effect is highly unpredictable. Many factors affect the delivery of drugs to specific regions of the body. For example, Sabate et al. (1996, Clinical Neuroscience 3:317-321) teaches that the blood brain barrier prevents access to the brain of numerous macromolecules of therapeutic value. Delivery of such molecules requires intracerebral or intracerebroventricular injection, and infusion using osmotic pumps when long-term treatments are needed. The combination of infectious risks and constraints of the delivery technique have precluded the generalized use of such drugs. The instant specification does not demonstrate delivery of an amount of any therapeutic agent sufficient to produce a therapeutic effect, using the claimed method. Further, the state of the art is such that a variety of factors affect therapeutic outcome, including method of delivery,

Art Unit: 1632

site of delivery, composition uptake, composition half-life, and composition concentration and mode of action. Further, it is reasonable to expect that different combinations of channel agonist and medicant will have varying degrees of effect. Thus, given the unpredictability in the art, the limited guidance in the specification, the lack of any working examples that demonstrate production of a therapeutic effect, one of skill in the art would be required to engage in undue experimentation to practice the claimed invention to achieve a therapeutic effect.

Conclusion

No claims are allowed.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Friday from 10:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (571) 272-0804. The central official fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Art Unit: 1632

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk
ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER